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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,259	08/11/2006	Shoufeng Li	PA/4-33279A	7673

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EXAMINER	
DANG, IAN D	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
12/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,259	LI ET AL.	
	Examiner	Art Unit	
	Ian Dang	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *12-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/10/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Exhibit A*.

DETAILED ACTION

Election/Restrictions

It is noted that the three inventive groups disclosed on page 2 of Applicant's response of 16 November 2007 are not correct. The 3 groups representing patentably distinct inventions put forth in the Office action of 05 October 2007 and reiterated herein below are:

Group I, claim(s) 1-11, drawn to a solid pharmaceutical composition suitable for the oral delivery of a pharmacologically active agent comprising a) a therapeutically-effective amount of a pharmacologically active agent, b) pharmaceutically acceptable inactive excipients, and c) a delivery agent for said pharmacologically active agent.

Group II, claim(s) 12, drawn to a method for enhancing the oral bioavailability of a pharmacologically active agent comprising administering to a patient in need of a pharmacologically active agent.

Group III, claim(s) 13-15, drawn to a method of treatment of bone related diseases and calcium disorders comprising administering to a patient in need of such treatment a therapeutically effective amount of a composition.

Applicant's election with traverse of Group I, claims 1-11 in the communication filed on 11/16/2007 is acknowledged.

The traverse is on the grounds that Leone-Bay et al. (US Patent No. 5866,536) does not disclose the present common technical feature and a person skilled in the art would not be motivated to modify Leone-Bay in such a way as to produce the presently common technical feature.

Applicant's arguments have been fully considered but are not found persuasive. The term micronized particles is defined as particles that are only a few micrometers in diameter

(see attachment A). Leone-Bay et al. (US Patent No. 5866,536) disclose that the compounds I-CXXIII or polyamino acids or peptides that include at least one of these compounds may be used directly as a delivery carrier and the compounds, polyamino acids, or peptides may be used to form microspheres containing the active agent (column 21, lines 16-23). In addition, Leone-Bay et al. teach that the particle size of the microsphere plays an important role in determining release of the active agent in the targeted area of the gastro-intestinal tract. The preferred microspheres have diameters between about 0.1 microns and about 10 microns, preferably between about 0.5 microns and about 5 microns. The microspheres are sufficiently small to release effectively the active agent at the targeted area within the gastro-intestinal tract such as, for example, between the stomach and the jejunum (Column 22, lines 52-60). The teachings of Leone-Bay et al. meet the limitations of claim 1 teaching the micronized form of the delivery agent. Thus, Group I lacks novelty or inventive step and does not make a contribution over the prior art. Since the first claimed invention has no special technical feature, it cannot share a special technical feature with the other claimed invention.

Claims 12-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-11 are pending and under examination.

Specification

The abstract of the disclosure is objected to because the abstract uses legal terminology ("said"). Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 112

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "therapeutically effective amount" in claims 1-11 is a relative term which renders the claims indefinite. The term "therapeutically effective amount " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear what disease/disorder/condition the salmon calcitonin composition is intended to treat. The therapeutic goal of the administration of the salmon calcitonin composition is not defined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1, 2, 3, 4, 8, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Leone-Bay et al. (US Patent No. 5866,536).

Leone Bay et al., (US Patent 5,866,536, filed 02/06/1997, issued 02/02/1999) teach a composition comprising an active agent (claim 6, column 35), excipient (claim 8, column 36; column 23, lines 56-57), and a delivery agent or carrier agent (claim 6, column 35). In addition, Leone-Bay et al. (US Patent No. 5866,536) disclose that the compounds I-CXXIII or polyamino acids or peptides that include at least one of these compounds may be used directly as a delivery carrier and may be used to form microspheres containing the active agent (column 21, lines 16-23). In addition, Leone-Bay et al. teach that the particle size of the microsphere plays an important role in determining release of the active agent in the targeted area of the gastro-intestinal tract. The preferred microspheres have diameters between about 0.1 microns and about 10 microns, preferably between about 0.5 microns and about 5 microns (Column 22, lines 52-60). It is well known in the art the time of filing that the term "micronized" is defined as the production of particles that are only a few micrometers in diameter (see the enclosed definition of micronization as Exhibit A). Thus, the teachings of Leone-Bay et al. (US Patent No. 5866,536) meet the limitations of claim 1.

In addition, Leone-Bay et al. (US Patent No. 5,866,536) teach that the biologically active compound is a peptide (column 35, line 44, claim 3), meeting the limitations of claim 2. Leone-

Bay teach that the active agent may be calcitonin, in particular salmon calcitonin, meeting the limitations of claims 2-4 (column 17, lines 23-43; column 32).

Finally, Leone-Bay et al. recite that the composition comprises a diluent and a lubricant (see claim 8, column 36, and column 23, lines 56-57 of US Patent No. 5,866,536) meeting the limitations of claims 8 and 10 of the instant application..

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 5-7, 9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leone-Bay et al. (US Patent No. 5866,536, filed February 6, 1997, issued February 2, 1999) as applied to claims 1-4, 8, and 10 in view of Ault et al., (US Patent 7,049,283; Filed December 4, 2001; published September 5, 2002).

The teachings of Leone-Bay et al. (US Patent No. 5,866,536, filed February 6, 1997, issued February 2, 1999) are set forth above. However, the reference does not teach that the inactive excipient is crospovidone or povidone; a delivery agent selected from the group consisting of 5-CNAC, SNAD, SNAC, a disodium salt of 5-CNAC, a disodium salt of SNAD, or a disodium salt of SNAC. Leone-Bay et al. does not teach the diluent, microcrystalline cellulose, or the lubricant, magnesium stearate.

Ault et al., (US Patent 7,049,283; Filed December 4, 2001; published September 5, 2002) teach a composition comprising a solid salmon calcitonin; the inactive excipient, crospovidone or povidone; and the delivery agent 5CNAC, SNAD, or SNAC (or disodium salts thereof) (column 11, lines 28-31, claim 1; column 2, lines 8-18; column 3, lines 60-67; column 4, lines 1-29; column 5, lines 60-67). In addition, Ault et al. further teach the composition comprises the diluent, microcrystalline cellulose, and the lubricant, magnesium stearate (column 12, lines 13-15, claim 1; column 6, lines 11-19).

Thus, it would be obvious for one skilled in the art to modify a solid pharmaceutical composition comprising salmon calcitonin, an inactive excipient, and a delivery agent in micronized form as taught by Leone-Bay et al. (US Patent No. 5866,536, filed February 6, 1997, issued February 2, 1999) by utilizing the inactive excipient, crospovidone or povidone; the delivery agent 5CNAC, SNAD, or SNAC (or disodium salts thereof); the diluent, microcrystalline cellulose, and the lubricant, magnesium stearate as taught by Ault et al.. One of ordinary skill in the art at the time the invention was made would been motivated to utilize the agents of Ault et al. in the composition of Leone-Bay et al. (with a micronized delivery agent) because the pharmaceutical compositions of Ault et al. enhance the oral bioavailability of pharmacologically active agents (Ault et al., column 2, lines 1-11) and micronization plays an important role in determining release of the active agent in the targeted area of the gastro-intestinal tract (Leone-

Bay et al., column 22, lines 52-54). One skilled in the art would have expected success because pharmaceutical composition with micronized hydrophobic agents were available and practiced at the time the invention was made. Accordingly, the invention taken as a whole is prima facie obvious.

Conclusion

No claim is allowed.

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ian Dang whose telephone number is (571) 272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang
Patent Examiner
Art Unit 1647
December 6, 2007

/Bridget E Bunner/
Primary Examiner, Art Unit 1647